IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: CYCLOBENZAPRINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULE PATENT LITIGATION	C.A. NO. 09-MD-2118-SLR
EURAND, INC., CEPHALON, INC., and ANESTA AG, Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., MYLAN INC. and BARR LABORATORIES, INC., Defendants.	C.A. NO. 08-889-SLR

PLAINTIFFS' OPPOSITION TO MYLAN'S EMERGENCY MOTION FOR RECONSIDERATION OF THE COURT'S MAY 20 MEMORANDUM ORDER

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I. INTRODUCTION

In its emergency motion for reconsideration of the Court's May 20, 2010 order ("Order"), Mylan does nothing more than reargue its previous positions and disagree with the Court's decision to grant temporary injunctive relief. But Mylan's displeasure with the Court's decision is not sufficient to support a motion for reconsideration. Thus, Mylan's motion for reconsideration should be denied and, to maintain the *status quo* as it existed before Mylan launched its generic products at risk, Mylan should be enjoined during the dependency of the appeal of the Court's decision.

Mylan's motion does not acknowledge or address the high legal standard for reconsideration. This Court has repeatedly held that "[t]he standard for obtaining relief under Rule 59(e) is difficult to meet." *Schering-Plough Healthcare Prods. v. Neutrogena Corp.*, No. 09-642-SLR, 2010 WL 2788240, at *1-2 (D. Del. July 15, 2010). Even when the standard is met, the Court "***may exercise its discretion*** to alter or amend its judgment." (*Id.* (emphasis added).) Mylan's request for reconsideration does not present a situation that meets the high standard for reconsideration and, accordingly, there is no basis for the Court to exercise its discretion here.

The Court's decision to grant injunctive relief was fully justified. Although Mylan argues that the Court erred under the Third Circuit standard, Federal Circuit law applies to grants of injunctive relief in patent cases. *See, e.g., Laboratory Corp. of Am. Holdings v. Chiron Corp.*, 384 F.3d 1326, 1330-31 (Fed. Cir. 2004) ("In this case, the decision whether to follow Federal Circuit or Third Circuit law is critical . . . Our conclusion that Federal Circuit law applies is consistent . . . with our precedent governing the review of the grant or denial in other cases of injunctions directed to substantive issues in patent cases under Federal Circuit law."). Under Federal Circuit precedent, the movant need only show that it will be irreparably harmed,

that it has a likelihood of success on appeal, and that the balance of injunctive relief factors weigh in the movant's favor. That is what Plaintiffs showed and that is exactly what the Court found.

With respect to irreparable harm, the Court found that it was "most assured . . . that Plaintiffs would suffer irreparable harm if a restraining order is not granted." (D.I. 273 at 6, ¶ 11.) Mylan does not contest this. The Court further found that any harm to Mylan was self-inflicted by Mylan's decision to launch its generic products at risk less than twenty-four hours after this Court's May 12, 2011 Opinion. (*Id.* at 6, ¶ 12.)

With respect to the likelihood of success on appeal, the Court acknowledged errors in its post-trial opinion finding the asserted claims obviousness and then explicitly found that this factor "marginally ***supports a temporary restraining order***." (*Id.* at 6, ¶ 10 (emphasis added).) Thus, Mylan is simply wrong that the Court did not find that the likelihood of success on appeal factor supports granting the TRO. (D.I. 275 at 2.) In addition, as explained below, Plaintiffs likelihood of success on appeal is high because even the additional findings in the Court's May 20 Order do not cure the errors in the Court's original obviousness analysis.

Therefore, the Court's May 20 Order was more than sufficient to support a grant of injunctive relief. Mylan's effort to undo it should be denied.

A. Defendants Ignore—and Have Not Met—the Standard for a Motion for Reconsideration

This Court has repeatedly held that "[t]he standard for obtaining relief under Rule 59(e) is difficult to meet," and that even when the standard is met (which it is not here), the Court "***may exercise its discretion*** to alter or amend its judgment." *Schering-Plough Healthcare Prods. v. Neutrogena Corp.*, No. 09-642-SLR, 2010 WL 2788240, at *1-2 (D. Del. July 15, 2010).[1] A

[1] This Court rarely grants motions for reconsideration. *See, e.g., QVC, Inc. v. Your Vitamins,*

court may, ***in its discretion***, alter or amend its judgment if the movant demonstrates at least one of the following: (1) a change in the controlling law; (2) availability of new evidence not available when the court issued its order; or (3) a need to correct a clear error of law or fact or to prevent manifest injustice. *Max's Seafood Cafe v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999); *Schering-Plough*, 2010 WL 2788240, at *1-2. "A motion for reargument is not properly premised on a request that a court rethink a decision already made." *OSI Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 09-185-SLR, 2011 WL 892349, at *1 (D. Del. Mar. 11, 2011). Instead, "[t]he purpose of a motion for reargument or reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence." *Id.* (citing *Max's Seafood,* 176 F.3d at 677).

Tellingly, Mylan did not even address this standard in its opening brief, no doubt because none of the three predicate situations that would permit reconsideration is present here. Mylan cannot point to a change in controlling law or new evidence since the Court issued its Order

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Inc., No. 10-094-SLR, 2010 WL 4919, at *1 (D. Del. Nov. 29, 2010) ("***Plaintiffs' chief complaint is that the court did not weigh the facts of record as plaintiffs would have wanted***. . . . ***Such is insufficient to meet the motion for reconsideration standard***. . . . ***[t]he standard for obtaining relief under Rule 59(e) is difficult to meet*** . . . a court ***may exercise its discretion*** to alter or amend its judgment if the movant demonstrates one of the following [three relevant factors]." (emphasis added)); *Principal Life Insur. Co. v. Rucker 2007 Insur. Trust*, 735 F. Supp. 2d 130, 146-47 (D. Del. 2010) ("motions [for reconsideration] are granted sparingly … and in narrow circumstances. . . . reargument should not be granted where it would merely allow wasteful repetition of arguments already briefed, considered and decided, nor should this procedural device be permitted to allow for endless debate between the parties and the court."); *Callaway Golf Co. v. Dunlop Slazenger Group Ams., Inc.*, 325 F. Supp. 2d 457, 459 (D. Del. 2004) ("'Motions for reconsideration should be granted only sparingly. . . . Courts should be particularly vigilant that motions for reargument or reconsideration are not used as a means to argue new facts or issues that inexcusably were not presented to the court in the matter previously decided."); *Oglesby v. Penn Mutual Life Insur. Co.*, 877 F Supp. 872, 896 (D. Del. 1994) ("Plaintiff's motion for reargument amounts to nothing more than a disagreement with this Court's considered application of Delaware law to the record. . . . Accordingly, plaintiff's motion for reargument will be denied."); *Brambles USA, Inc. v. Blocker*, 735 F. Supp 1239, 1240 (D. Del. 1990) ("The procedural mechanism afforded by Local Rule 3.3 should not be undermined to allow for endless debate between the parties and the Court. . . . this Court's opinions are not intended as mere first drafts, subject to revision and reconsideration at a litigant's pleasure.").

granting Plaintiffs' Motion for a TRO. Mylan's appears to argue that the Court committed a clear error of law or fact, but it did not.

The Court has broad discretion in evaluating the four-factor test for injunctive relief and making the ultimate decision whether or not to grant injunctive relief. *See Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1334 (Fed. Cir. 2006) ("The decision to grant or deny a preliminary injunction is within the sound discretion of the district court.") And, as explained below, the Court correctly found that Plaintiffs would suffer irreparable harm in the absence of injunctive relief and that the likelihood of success on the merits "marginally ***supports a temporary restraining order***." (D.I. 273 at 6, ¶¶ 10, 11 (emphasis added).) These findings, plus a finding that the balance of harms factor favors Plaintiffs, is all that is required for injunctive relief under Federal Circuit precedent. Since the Court's order included those findings, Mylan's motion should be denied.

B. The Court's Decision to Grant Temporary Injunctive Relief was Proper

The parties agree that courts examine four factors when considering a motion for temporary injunctive relief: (1) the likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) the balance of hardships; and (4) the injunction's impact on the public interest.[2] *See Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). Under Federal Circuit law, these factors "are not applied mechanically" and a movant only has to establish the existence of the first two factors to support a preliminary injunction. *See, e.g., id; Altana Pharma AG v. Teva Pharms. USA,* Inc., 566 F.3d 999, 1005

[2] Plaintiffs have also moved for injunctive relief pending appeal pursuant to Fed. R. Civ. P. 62(c). (D.I. 271.) Courts consider similar factors when deciding a motion for injunction pursuant to Fed. R. Civ. P. 62(c). *See Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990).

(Fed. Cir. 2009).[3]

As explained below, the Court correctly found that the factors weigh in favor of Plaintiffs. As a result, the Court's decision to grant Plaintiffs' motion for temporary injunctive relief was appropriate, and it is therefore appropriate for the Court to enter an injunction pending appeal to maintain the *status quo* as it existed before Mylan's launch at risk.

1. Under Federal Circuit Law, the Court's Findings Justify Temporary Injunctive Relief

As explained above, under Federal Circuit law, a movant need only establish that the first two factors weigh in its favor, namely a likelihood of success on the merits and irreparable harm, and that the balance of injunctive relief factors weigh in the movant's favor. *See, e.g., Amazon.com,* 239 F.3d at 1350. Here, the Court explicitly made such findings and, as explained below, those findings were correct.

First, the Court found that "Plaintiffs will suffer irreparable harm if a restraining order is not granted" based on Plaintiffs' potential price erosion, reduction of workforce, reduction of research funding and loss of consumer goodwill. (D.I. 273 at 2, ¶ 3 and 6, ¶ 11.) The Court also rejected Mylan's argument that the harm to Plaintiffs has already occurred and cannot be cured

[3] In patent cases, the district court's decision to grant, deny, or modify an injunction is controlled by Federal Circuit law, not regional circuit law. *See Laboratory Corp. of Am. Holdings v. Chiron Corp.*, 384 F.3d 1326, 1330-31 (Fed. Cir. 2004) ("In this case, the decision whether to follow Federal Circuit or Third Circuit law is critical . . . Our conclusion that Federal Circuit law applies is consistent . . . with our precedent governing the review of the grant or denial in other cases of injunctions directed to substantive issues in patent cases under Federal Circuit law."); *Int'l Rectifier Corp. v. Samsung Elecs. Co.*, 361 F.3d 1355, 1359 (Fed. Cir. 2004); *MedPointe Healthcare, Inc. v. Hi-Tech Pharmacal Co.*, 115 Fed. Appx. 76, 78 (Fed. Cir. 2004) (*citing Laboratory Corp.* and *Int'l Recifier*). Accordingly, the Third Circuit cases cited by Mylan for the proposition that "failure to establish any element in plaintiffs' favor renders a preliminary injunction inappropriate" do not apply here. (D.I. 275 at 1.) Moreover, even if Third Circuit law applied, a TRO is still warranted here. See, *Kos Pharms, Inc. v. Andrx Corp.*, 369 F.3d 700, 730 (3d. Cir. 2004) ("As a practical matter, if a plaintiff demonstrates both a likelihood of success on the merits and irreparable injury, it almost always will be the case that the public interest will favor the plaintiff.").

by temporary injunctive relief. (*Id*.) The Court's conclusion is not subject to reasonable dispute, and Mylan does not argue to the contrary in its motion for reconsideration.

Second, after acknowledging several errors in its obviousness analysis, the Court found that the likelihood of success on the merits factor "***supports a temporary restraining order***." (D.I. 273 at 6, ¶ 10 (emphasis added).) Mylan ignores the Court's explicit finding that the likelihood of success factor ***supports*** a TRO so that it can engage in reargument of the facts and law already considered by the Court in granting the TRO motion. This is improper. *See OSI Pharms.*, 2011 WL 892349, at *1. Because the decision granting a TRO was fully supported, the Court should not reconsider it.

Rather than acknowledge ***the Court's explicit finding that this factor favors Plaintiffs,*** Mylan focuses on the Court's statement that "plaintiffs' success on appeal is just as likely as not." (D.I. 275 at 1-2.) Mylan attempts to rewrite the Court's order to say that Plaintiffs' chances of prevailing on appeal are "50-50," but nothing in the opinion suggests that the Court intended to handicap the parties' odds with such mathematical precision. The Court's ultimate conclusion that this element supports plaintiffs—albeit only "marginally" in the Court's view—is all that the law requires.[4]

[4] Moreover, for motions under Rule 62(c), "[w]hen harm to the applicant is great enough, a court will not require 'a strong showing' that applicant is 'likely to succeed on the merits.'" *Standard Havens*, 897 F.2d at 513. Rather, the Federal Circuit has stated that courts should employ a flexible approach in which the likelihood of success is balanced against the harm faced by the moving party. *See id*. at 513 (recognizing that the four factors "can effectively merge, as our court implicitly recognized in *DuPont*, saying '[i]n considering whether to grant [relief] pending appeal, this court assesses the movant's chances for success on appeal and weighs the equities as they affect the parties and the public") (internal citation omitted); *see also Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co*., 2004 WL 1305849, at *21 (D. Del. June 9, 2004) ("The four factors often effectively merge as the likelihood of success is weighed with the equities affecting the parties and the public."). Because Plaintiffs would suffer irreparable harm if Mylan's launch is not enjoined pending appeal, Plaintiffs do not need to make a strong showing that they are likely to succeed on the merits.

The Court's conclusion is justified because there is a substantial likelihood that the Federal Circuit will conclude that Mylan did not meet its heavy burden of overcoming the presumption of validity and proving obviousness by clear and convincing evidence. *See, e.g. Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997) ("In order to demonstrate that it has a likelihood of success, Genentech must show that, in light of the presumptions and burdens that will inhere at trial on the merits . . . its infringement claim will likely withstand Novo's challenges to the validity and enforceability of the '199 patent."); *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988) ("The clear and convincing standard of proof of facts is an intermediate standard which lies somewhere between beyond a reasonable doubt and a preponderance of the evidence."). That is particularly true in this case where it has already been shown, and is not contested, that there were factual and legal errors in the Court's May 12 post-trial opinion. Indeed, as discussed below, the additional findings the Court made in addressing the errors in its May 12 opinion in fact compound the problems and further undercut Mylan's chances of success on appeal. Once again, Mylan cannot ignore the substantial likelihood that the Federal Circuit will conclude that, absent the benefit of those errors, Mylan did not and could not satisfy its heavy burden of proof.

Third, the Court correctly found that any harm to Mylan from a temporary restraining order is "minimal." (D.I. 273 at 6, ¶ 12.) Specifically, the Court found Mylan's arguments regarding its 180-day exclusivity period unpersuasive because Mylan "knew this was an 'at risk launch'" and "bore the risk of a restraining order both from this court and the Federal Circuit." (*Id*.) In its motion for reconsideration, Mylan simply reargues that the loss of its exclusivity period is "irreparable" and that the Court could not correctly conclude that the (undisputed)

irreparable harm to Plaintiffs would outweigh the harm to Mylan.[5] (D.I. 275 at 3.) Mylan does not address the basis for the Court's finding on this factor—that any harm to Mylan is a result of its own actions. As the Court found, it was Mylan's decision to launch its ANDA products almost immediately after the Court's decision "despite the fact that the court found that defendants infringed the patents-in-suit, and plaintiffs had not exhausted their appeals."[6] (D.I. 273 at 6-7, ¶ 12.) The Court therefore correctly concluded that this factor favors the grant of temporary injunctive relief.

Moreover, the Federal Circuit itself has granted injunctive relief to preserve the *status quo* pending appeal under similar circumstances. *Eli Lilly and Co. v. Actavis Elizabeth LLC*, No. 2010-1500, 2010 WL 3374123 (Fed. Cir. 2010). In *Eli Lilly v. Actavis*, the Federal Circuit granted Eli Lilly's motion for an injunction pending appeal ***after*** the district court found the claims of Eli Lilly's patent infringed but invalid. *Id*. at *1. The Federal Circuit granted Eli Lilly's motion to preserve the *status quo* by preventing the introduction of Actavis's generic version of the branded product. *Id*.

2. The Court's Further Explanation of its Obviousness Analysis Does Not Cure the Significant Problems with that Analysis

In support of their TRO motion, Plaintiffs pointed to material errors in the Court's obviousness analysis without which the Court's obviousness conclusion could not stand. (D.I. 257; D.I. 262.) In its May 20 Order, the Court adopted several of Mylan's obviousness

[5] Mylan does not cite any cases that find a loss of exclusivity period "irreparable" where a generic company launched "at risk" and then was required to restore the *status quo*. Mylan does cite several cases to support the proposition that its harm would be "irreparable" but they involve the very different and inapplicable scenario where multiple generic companies dispute the right to an exclusivity period in the first instance. (D.I. 275 at 2-3 (*citing Apotex, Inc. v. FDA*, No. Civ. A. 06-0627 JDB, 2006 WL 1031051 (D.D.C. Apr. 19, 2006); *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 32-33 (D.D.C. 2006); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998); *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20 (D.D.C. 1997).)

[6] Moreover, Plaintiffs have agreed to join in a request to expedite the appeal of the Court's decision (D.I. 274).

arguments that it had not adopted in its May 12 Order, and made some new findings in support of its obviousness conclusion. (*See* D.I. 273 at ¶¶ 5-9.) Notwithstanding its attempt to address its errors, the Court found that the likelihood of success on the merits supports granting a temporary restraining order. (*Id.* at ¶10.)

Respectfully, the Court's additional findings and clarifications do not cure the errors in the Court's May 12 post-trial opinion and, in fact, raise additional questions about the bases for the Court's obviousness conclusion. The Court's additional findings do not support a determination of obviousness for at least the following reasons:

- Dr. Weiner testified that both the inventors and a person of ordinary skill in the art would choose a ***two-compartment model*** in attempting to develop an extended-release pharmacokinetic profile for cyclobenzaprine, and that T_{max} ***could not be calculated*** in such models

- It was not "harmless" for the Court to rely on the testimony of Dr. Fletcher to "fill in the gaps" in the prior art because the additional testimony cited by the Court does not corroborate Dr. Fletcher's testimony

- The claimed C_{max} is not "undisputably disclosed" in Winchell and there is no reliable evidence supporting the conclusion that the other values can be obtained via routine experimentation from Winchell

- The inventors did not simply "verify [their] results in the lab" but instead Plaintiffs spent millions of dollars over a period of several years undertaking human clinical trials to determine whether their formulation was safe and efficacious

- The Court's importation of a factual finding from the *Purdue Pharma* case (which involved a different drug and set of circumstances) to support a finding that the claimed inventions are obvious is improper

Plaintiffs addressed some of these issues in their motion for relief from judgment, which was filed just hours before the Court issued its May 20 order. (D.I. 271.) To the extent the Court's May 20 Order raises new issues, Plaintiffs address them below. None of the Court's additional discussion in the May 20 Order can cure the fact that Mylan simply failed to prove

obviousness by clear and convincing evidence.

a. Paragraph 5 of the Court's TRO Order

In paragraph 5 of the May 20 Order, the Court acknowledged "that it erred when it stated that Weiner made the admission that T_{max} was calculable, when in fact the statement was made by Fletcher." (D.I. 273 at ¶ 5.) The Court went on to find, however, that Plaintiffs' expert, Dr. Weiner, "did admit that his program, WinNolin, has the capability of computing the T_{max} in some models when other parameters of the model are known" and that "[t]his testimony, combined with that of Fletcher, supports the court's finding that T_{max} is a calculable value." (*Id.*) Respectfully, this conclusion is contradicted by the record.

Dr. Weiner's testimony that WinNonlin could compute T_{max} in some models does not lead to the conclusion that T_{max} is a calculable value when ***modeling an extended-release pharmacokinetic profile for cyclobenzaprine***. Dr. Weiner testified that a person of ordinary skill in the art would choose a ***two-compartment model*** (as the inventors did) in attempting to develop an extended-release pharmacokinetic profile for cyclobenzaprine:

> Q. Were you aware the Dr. Venkatesh testified . . . "[t]his suggests that we need to use ***a two-compartment model***."
> A. I see that.
>
> Q. That is what anybody in the skill of art would conclude?
> A. Yes, but there are many, many, many two-compartment models.

(D.I. 224 at 1268:18-1269:5; *see also id*. at 1340:13-1341:4.) Dr. Wiener further testified, both on cross examination and on redirect examination, that T_{max} could not be calculated in a two-compartment model:

> Q. But you are not disputing that people of skill in the art calculate T_{max} from constants like that all the time; right, Doctor?
> A. No.
>
> Q. You're not disputing it?
> A. I am disputing it.

Q. Okay. But they talk about making the calculation in this book and in the other one; correct?
A. ***This model is not the model that was used by the inventors in the patent***.

*****

Q. Okay. I'm talking to you generally. Can people of skill in the art make a mathematical calculation of T_{max} based on other constants?
A. Only for the simplest of models.

Q. Okay.
A. That's the only one.

Q. Okay.
A. ***Not for two compartment models***.

(*Id*. at 1285:10-1286:9 (emphasis added); *see also id.* at 1340:13-1341:4.) Thus, according to Dr. Weiner, the inventor of WinNonlin, a person of ordinary skill in the art could not calculate T_{max} in developing an extended-release pharmacokinetic profile for cyclobenzaprine, and such an exercise would not necessarily lead to the claimed T_{max}, even assuming a known C_{max} and AUC.

Dr. Fletcher's testimony does not support the Court's conclusion either because, as explained in Plaintiffs' TRO briefing and in Plaintiffs' opening brief in support of its motion for relief from judgment, (1) Dr. Fletcher is not a person of ordinary skill in the art and (2) Dr. Fletcher's testimony that the claimed T_{max} could be "calculated" was outside the scope of his expert report and thus not vetted during discovery. (D.I. 257 at 6-7; D.I. 262 at 8-9; D.I. 271 at 5-7, 13-17.) In addition, even considering his testimony on T_{max}, Dr. Fletcher never testified ***what value would result*** from the supposed T_{max} "calculation" ***or whether that value would fall within the claimed range***.[7]

[7] The only other expert testimony offered by Defendants about the claimed T_{max} was Dr. Amidon's, who despite testifying that he "did it the way a person skilled in the art would do," calculated a T_{max} in his corrected expert report that fell ***outside the claimed ranges***. (D.I. 222 at 880:10-882:5; D.I. 223 at 1187:20-1191:7; DTX-458.)

Because neither Dr. Fletcher's nor Dr. Weiner's testimony supports the conclusion that T_{max} is a calculable value in the context of the invention of the patents-in-suit, the additional findings in paragraph 5 of the Court's TRO order do not support a finding of obviousness.

b. Paragraph 6 of the Court's TRO Order

In paragraph 6 of the Court's May 20 Order, the Court stated that [a]ssuming, arguendo, that it was improper for the court to rely on Fletcher's testimony to fill in the gaps in the disclosures of the prior art, the error is harmless as much of his testimony was corroborated by defendants' other expert, Dr. Gordon Amidon ("Amidon"), and/or Weiner himself." (D.I. 273 at 4, ¶ 6.) The Court's explanation on this issue compounds, rather than cures, the error in the Court's original opinion.

First, Dr. Amidon did not corroborate Dr. Fletcher's testimony at trial. Although Dr. Amidon opined on designing an extended-release profile in his expert report, Defendants did not present Dr. Amidon's testimony on this topic at trial because Dr. Amidon arrived at a pharmacokinetic profile, based on modeling performed using data from Winchell, with a C*max*, AUC, and T*max* that ***fell outside the claimed ranges***. (D.I. 222 at 880:10-882:5; D.I. 223 at 1187:20-1191:7; DTX-458.)

Second, Dr. Weiner's statements that the claimed C_{max} and $AUC_{0\text{-}168}$ of the patents in suit "are inherent to FLEXERIL®" is irrelevant because Dr. Weiner's statement was based on Plaintiffs' clinical studies, ***that are not prior art***, comparing FLEXERIL to AMRIX®.[8] (D.I. 260 at 11.) That leaves only Dr. Clevenger's testimony, and as the Court acknowledges, it is

[8] Contrary to the Court's findings, the immediate-release form of cyclobenzaprine available since 1977 has never been sold by Plaintiffs. (D.I. 273 at 4, ¶ 6.) Moreover, inherency is strictly a doctrine of anticipation, and does not have any place in the obviousness analysis: "Inherency and obviousness are distinct concepts." *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1576 (Fed. Cir. 1986) (citing *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 1555 (Fed.Cir.1983).)

legal error to solely rely on what the inventors did in finding obviousness.

Thus, the additional findings in paragraph 6 of the Court's TRO order do not support the conclusion that it was harmless error to rely on the testimony of Dr. Fletcher in "fill[ing] in the gaps" in the prior art, and those findings do not support an obviousness determination.

c. Paragraph 7 of the Court's TRO Order

In paragraph 7 of the TRO Order, in attempting to clarify its statement that the claimed PK constants were disclosed by Winchell, the Court stated that:

> The claimed C_{max} is undisputably disclosed, and the other values can be obtained via routine experimentation from the Winchell and Hucker references as well as plaintiffs' FLEXERIL® product.

(D.I. 273 at 4, ¶ 7.) Again, this explanation does not cure the original error.

First, it is not "undisputed" that the claimed C_{max} is disclosed in the Winchell reference. As the Court acknowledged, the values in Winchell are steady state values, not single dose values, and, when it comes to comparing pharmacokinetic values, that is a "distinction with a difference." Moreover, the steady state C_{max} disclosed in the Winchell reference (25.9 ng/ml) does not fall within 80% to 125% of 20 ng/ml (it falls 4.5% outside that range). Therefore, whether the C_{max} disclosed in Winchell falls within the claimed range depends on the claim construction of the word "about." The Court expressly rejected Defendants' construction of "about," which provided for "about" to encompass a range of ±5%, and adopted Plaintiffs' construction of the term that was the ordinary meaning or "approximately." (D.I. 254 at 11-12.) There was no testimony at trial, from either party, supporting the conclusion that 129.5% of 20 ng/mL is "approximately" 125% of 20 ng/mL.

Second, obtaining the other values would not be "routine experimentation from the Winchell and Hucker references as well as plaintiffs' FLEXERIL® product" at least because the

Court appears to rely on Plaintiffs' studies comparing FLEXERIL® to AMRIX®, ***which are not prior art***. (D.I. 260 at 11.) Moreover, the only trial testimony that even suggested this is the case was from Dr. Fletcher, who, as explained above, is not a person of ordinary skill in the art. Finally, the Court again cites the work of the inventors, which is not a proper basis for a finding of obviousness. *See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008) (holding that simply retracing the path of the inventor with hindsight is inappropriate in the context of an obviousness analysis).

Thus, the additional findings in paragraph 7 of the Court's TRO order do not support a conclusion that the claimed pharmacokinetic values were disclosed by Winchell and do not support a determination of obviousness.

d. Paragraph 8 of the Court's TRO order

In paragraph 8 of the May 20 Order, the Court stated that testimony of Dr. Clevenger cited by Plaintiffs in their TRO briefing "simply shows that the inventor needed to verify his results in the lab." (D.I. 273 at 5, ¶ 8.) This clarification greatly oversimplifies the relevant facts and does not support the Court's finding of obviousness.

Dr. Clevenger could not simply "verify his results in the lab." (*Id.*) Plaintiffs spent millions of dollars over a period of several years undertaking human clinical trials to determine whether their formulation was safe and efficacious. Moreover, Dr. Clevenger testified that the inventors could not predict if they had created a therapeutically effective extended-release cyclobenzaprine product until they went "to the clinic" because success "depend[ed] on the relationship between the blood levels and the therapeutic effect" (*i.e.*, the PK/PD relationship), ***which was unknown***. (D.I. 222 at 945:24-946:17.) Thus, Dr. Clevenger actually testified that the inventors did not expect to succeed in developing a therapeutically effective cyclobenzaprine extended release product because of the lack of a known relationship between blood levels and

therapeutic effect for cyclobenzaprine. (*Id.*) Last, the Court's finding again only relies on what the inventors did, which is an improper basis for a finding of obviousness. *Ortho-McNeil Pharm., Inc.*, 520 F.3d at 1364.

Thus, the additional findings in paragraph 8 of the Court's TRO order do not support a conclusion that Dr. Cleveger's testimony indicated that a person of ordinary skill in the art would have a reasonable expectation of success in developing a therapeutically effective extended-release cyclobenzaprine product and does not support a determination of obviousness.

e. Paragraph 9 of the Court's TRO order

In paragraph 9 of the May 20 Order, the Court stated that in its May 12 Opinion, it cited the *Purdue* case and Dr. Clevenger's testimony in support of the finding that "optimization" of an immediate-release pharmacokinetic profile was "routine" for one of ordinary skill in the art. (D.I. 273 at 5-6, ¶ 9.) These statements also do not support a finding of obviousness.

The Court's importation of a factual finding from the *Purdue Pharma* case (which involved a different drug and set of circumstances (*see* D.I. 238 at 28-31)) to support a finding that the inventions claimed in this case are obvious is improper. Beyond that, the Court relies on Dr. Clevenger's testimony, which again, by itself, cannot support a finding of obviousness.

Thus, the additional findings in paragraph 9 of the Court's TRO order do not support a finding of obviousness.

* * * * *

As demonstrated above, the Court's additional findings in its May 20 Order do not support a finding of obviousness. Thus, Plaintiffs have a high likelihood of success on appeal, especially in light of Mylan's burden to prove obviousness by clear and convincing evidence.

II. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Mylan's motion for reconsideration.

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